



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF: ANNA P. CATANIA *ET AL.*  
APPLICATION No.: 10/659,053  
FILED: SEPTEMBER 8, 2003  
FOR: **A COMPOSITION AND METHOD OF TREATMENT  
FOR UROGENITAL CONDITIONS**

EXAMINER:  
ART UNIT:  
CONF. No:

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

1. Timing of Submission

This information disclosure is being filed within three months of the filing date of this application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever occurs last [37 C.F.R. § 1.97(b)]. The references listed on the enclosed Form PTO-1449 (modified) may be material to the examination of this application; the Examiner is requested to make them of record in the application.

2. Cited Information

Copies of references marked by asterisks (i.e. A14, A15, and A16) have not been cited previously in the parent application. Because this application was filed after 30 June 2003, no copies of these U.S. patents are enclosed (See Notice of Deputy Commissioner Kunin on 11 July 2003).

Copies of all references not marked by asterisks can be found in parent U.S. Application No. 09/535,066 and/or in U.S. Application No. 10/442,683 to which Applicant also claimed priority.

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February 5, 2004  
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Debbie Gilbert  
Debbie Gilbert

3. Effect of Information Disclosure Statement (37 C.F.R. § 1.97(h))

This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

4. Fee Payment

No fees are believed due because this Information Disclosure Statement is being filed before the mailing date of the first Office Action.


However, should the Commissioner determine that fees are due in order for this Information Disclosure Statement to be considered, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-2586.

Dated: 2/5, 2004

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

Form PTO-1449 (Modified)  
(Use several sheets if necessary)

FEB 09 2004

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Application Number	10/659,053
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Filing Date	September 8, 2003
First Named Inventor	James M. LIPTON
Group Art Unit	
Examiner Name	
Attorney Docket No.	54275.8005.US03

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of

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**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No.	U.S. Patent or Application		Name of Patentee or Inventor of Cited Document	Date of Publication or Filing Date of Cited Document	Pages, Columns, Lines, Where Relevant Figures Appear
		NUMBER	Kind Code (if known)			
	A1	09/533,341		Catania Anna P. et al.	03/23/00	
	A2	09/957,765		Catania Anna P. et al.	09/21/01	
	A3	US-2002/0137685		Catania et al.	09/21/01	
	A4	60/200,287		Lipton, J.M.	04/28/00	
	A5	09/774,282		Lipton, J.M.	01/29/01	
	A6	09/828,272		Lipton, J.M.	04/06/01	
	A7	09/704,327		Lipton, J.M.	11/01/00	
	A8	5,028,592		Lipton, J.M.	08/05/88	
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	A10	US-2002/0146374		Lipton	01/29/01	
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	A18	10/420,578		Lipton et al.	04/21/03	
	A19	10/426,647		Lipton et al.	04/29/03	
	A20	10/298,142		Lipton	11/15/02	

**FOREIGN PATENT DOCUMENTS**

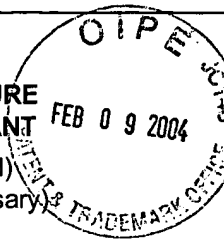
Examiner Initial	Cite No.	Foreign Patent or Application			Name of Patentee or Applicant of Cited Document	Date of Publication or Filing Date of Cited Document	Pages, Columns, Lines, Where Relevant Figures Appear	T
		Office	NUMBER	Kind Code (if known)				
	B1		EP 0972 522 A1		Mahe et al.	01/19/00		
	B2		FR 2,784,028			04/07/00		

EXAMINER

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(Use several sheets if necessary)



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B3		WO 97/10838		Mahe et al.	03/27/97		
B4		WO 93/01211		Rathjen et al.	01/21/93		
B5		PCT/US00/07846			03/23/00		
B6		WO 99/58101		Jarroussee et al.	11/18/99		
B7		WO 00/42856		Taylor et al.	07/27/00		

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<p align="center"><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p align="center">Form PTO-1449 (Modified) (Use several sheets if necessary)</p>				<b>COMPLETE IF KNOWN</b>	
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OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published.		
	C1	AIRAGHI, L., <i>et al.</i> , "Elevated concentrations of plasma $\alpha$ -MSH are associated with reduced disease progression in HIV-infected patients," <i>J. Lab. Clin. Med.</i> 133(3) 309-315 (1999).		
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	C4	ARMSTRONG, "The Microbiology of the Eye." <i>Ophthalm. Physiol. Opt.</i> 20: 429-503 (2000).		
	C5	AYLAD <i>et al.</i> , "Influence of Oral Acyclovir on Ocular Complications of <i>Herpes zoster ophthalmicus</i> ." <i>Eye</i> 8: 70-74 (1994).		
	C6	BAKER, M., <i>et al.</i> , "The Relationship between Interleukin-6 and Herpes Simplex Virus Type-1: Implications for Behavior and Immunopathology," <i>Brain Behav. Immun.</i> 13(3):201-11 (1999).		
	C7	BAKER, <i>et al.</i> , "Principles of Ambulatory Medicine," <i>Williams and Wilkins</i> (1982).		
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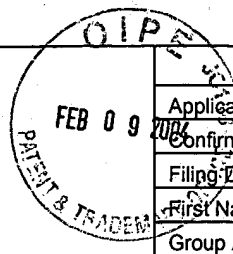
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C26	CAVELLO, J., <i>et al.</i> , "Sunburn," <i>Dermatologic Clinics</i> , 4(2): 181-187, 181 (1986).
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C29	CHIAO, H., <i>et al.</i> , "α-MSH reduces endotoxin-induced liver inflammation," <i>J. Clin. Invest.</i> 97: 2038-2044, (1996).
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Sheet	6	of	11
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C42	FITZPATRICK, <i>et al.</i> , "Acute Effects of Ultraviolet Radiation on the Skin: The Sunburn Reaction," <i>Dermatology in General Medicine</i> , 4th Edition, 1651-1655, 1651 (1993).
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C45	FOX, J. A., <i>et al.</i> , "Immunoreactive $\alpha$ -Melanocyte Stimulating Hormone, Its Distribution in the Gastrointestinal Tract of Intact and Hypophysectomized Rats," <i>Life. Sci.</i> 28, 2127-2132 (1981).
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C49	GOW, N.A., "Germ Tube Growth of <i>Candida albicans</i> ," <i>Curr. Topics Med. Myco.</i> 8, 43-55 (1997).
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C55	HILTZ, M.E., <i>et al.</i> , "α-MSH Peptides Inhibit Acute Inflammation Induced in Mice by rIL-1β, rIL-6, rTNF-α and endogenous pyrogen but not that cause by LTB <sub>4</sub> , PAF and rIL-8," <i>Cytokine</i> 4(4):320-328 (1992).
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C57	HUANG, <i>et al.</i> , "Role of central melanocortins in endotoxin-induced anorexia," <i>Am. J. Physio (Regulatory, Integrative &amp; Comparative Physiology)</i> , Vol. 276, No. 3, pgs R864-R871 (1999).
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C62	ICHIYAMA, T., <i>et al.</i> , "Autocrine α-melanocyte-stimulating hormone inhibits NF-κB activation in human glioma cells," <i>Journal of Neuroscience Research</i> 58:684-689,(1999).
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C65	ISHIBASHI & KAUFMAN, "The Effects of Subconjunctival Miconazole in the Treatment of Experimental <i>Candida</i> Keratitis in Rabbits." <i>Arch. Ophthalmol.</i> 103: 1570-1573 (1985).
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C67	LAZARUS <i>et al.</i> , "An <i>in vitro</i> Method Which Assesses Corneal Epithelial Toxicity due to Antineoplastic, Apreservative and Antimicrobial Agents." <i>Lens Eye Toxic. Res.</i> 6: 59-85 (1989).

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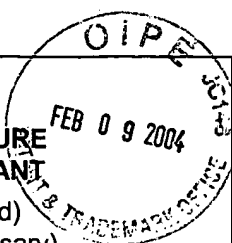
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